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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR               | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------------------|---------------------|------------------|
| 10/062,794  | 01/31/2002  | Arthur L. Rosenthal                | 10177-101           | 3444             |
| 7590 05/14/2004   |             |                                    |                     |                  |
| JONES DAY<br>222 East 41st Street<br>New York, NY 10017 |             | EXAMINER<br>JACKSON, SUZETTE JAMIE |                     |                  |
|   |             | ART UNIT<br>3738                   |                     | PAPER NUMBER     |
| DATE MAILED: 05/14/2004                                 |             |                                    |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/062,794 | <b>Applicant(s)</b><br>ROSENTHAL ET AL. |  |
|                              | <b>Examiner</b><br>Suzette J Jackson | <b>Art Unit</b><br>3738                 |  |

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Shanley Pub No. 2002/0068969. Shanley discloses the invention as claimed noting figure 6 comprising: A medical device (which is a stent 10) with a plurality of struts (18) and a plurality of non-structural elements integral with *and projecting from* the struts (32), wherein the struts and the non-structural elements comprise the biologically active material. [0038]; wherein the non-structural elements are configured in a shapes including hoops and ovals.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley in view of Harish et al. 6,506,437. While Shanley does state the use of biologically active material, Shanley does not specify the drugs. Harish et al. teaches the use of paclitaxel, dexamethasone, and actinomycin (see col. 6, lines 64 and col. 7, lines 5 and 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the drugs of Harish et al. into the stent of Shanley because they could treat individual dysfunction at the tissue in the vessel site depending upon the individual patients needs.

### ***Response to Arguments***

5. Applicant's arguments filed 2/17/04 have been fully considered but they are not persuasive. Applicant amends the claims to add the limitation of "...*and projecting from...*" The newly cited reference 2002/0068969 discloses the invention as claimed including "non-structural elements" which project from the struts. Applicant contends that the their definition of "nonstructural elements" as noted on page 8, line 20 of the specification incorporates the fact that "...such non-structural elements have substantially no effect on the mechanical properties of the struts, such as for example radial strength, longitudinal flexibility, expansion ratio, trackability etc.." It is noted that the applicants device is made of metal and as noted on page 8, line19 the non-structural elements are integral with the strut. Shanley's "non-structural" elements are

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also metal and formed integrally with the strut and as noted in section [0048] are non-deforming. The elements (30, 32) of Shanley do not have any effect on the mechanical properties and are only presented to carry a biologically active substance. Applicant is also directed to see MPEP 2111.01, which states:

Meaning THE WORDS OF A CLAIM MUST BE GIVEN THEIR "PLAIN MEANING" UNLESS THEY ARE DEFINED IN THE SPECIFICATION. While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); MSM Investments Co. v. Carolwood Corp., 259 F.3d 1335, 1339-40, 59 USPQ2d 1856, 1859-60 (Fed. Cir. 2001).

In light of this section of the MPEP, the term "non-structural" has been interpreted broadly as the claims reasonably allow.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sohler 2004/0006382; Burgermeister et al. 2003/0069630 ; and Shanley 2002/0107563 all show related material.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

8. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

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9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, reading "Suzette J. Jackson", with a long horizontal flourish extending to the right.

Suzette J. Jackson  
12 May 2004